

lene. The swab fibers optionally may be made from interbonded fibers, for example as of thermoplastic fibers. The term “fibers” as used herein refers to a broad range of thermoplastic members that can be used to form a nonwoven fabric, including members having defined lengths like staple fibers, meltblown fibers that show a beginning and an end, filaments having endless or continuous lengths, and the like. For example, and without limiting the generality of the foregoing, thermoplastic polymers such as polyolefins including polyethylene, polypropylene as well as polystyrene can be used as may be polyesters including polyethylene terephthalate, and polyamides including nylons. Also useful are other thermoplastic polymers such as those which are elastomeric including elastomeric polyurethanes and block copolymers. Compatible blends of any of the foregoing may also be used. In addition, additives such as wax, fillers, and the like may be incorporated in amounts consistent with the fiber forming process used to achieve desired results. Other fiber or filament forming materials will suggest themselves to those skilled in the art. Bicomponent fibers may be also used. The fibers may also be formed from solution, and examples include viscose. It is only essential that the composition be capable of spinning into filaments or fibers of some form that can be deposited onto a forming surface and thermally formed or interbonded in a manner dependent upon the forming surface. The swab tip may comprise a sponge element.

[0074] FIG. 3 shows a representative device for swab capture and analysis. FIG. 3A is a plan view of the top surface of the device, showing plane of section 3B and the location of the swab receiving orifice and sealing closure. In FIG. 3A, the device body 10 and exterior surfaces 11 are again shown.

[0075] FIG. 3B is a view of the internal workings of a representative device (30), showing a section through the device solid body interior (31), with captive swab tip (32) in swab receiving chamber (33), also termed herein an “internal hollow volume”. In this view, closure (34) and gasket (35) form a liquid-tight seal over the swab receiving chamber 33. Also shown in schematic form are the elements of an on-board nucleic acid assay. Generally, at least one valve (37) will separate the internal hollow volume of the device body into at least two compartments, one for the sample receiving chamber and the other the analytical microfluidics compartment or circuit (dotted lines with arrows, 42). Other valves (38) may also be used to add functionality to the microfluidic circuit. Any valve known in the art may be used. On-board microfluidic elements for a nucleic acid assay include at least one microfluidic channel (39), and optionally provision for reagent packs such as for lysis reagent and extract reagents (40,41), and an optional microfluidic nucleic acid assay circuit (42), shown schematically. In this embodiment, the internal hollow volume comprises a first compartment for receiving the swab (33) and a second compartment (42, dotted lines) for performing a fluidic operation on the sample, such as a sample preparation step or a sample analysis such as PCR. Generally, the first and second compartments are joined by a valved (37) microfluidic channel (39). This channel provides for fluidic connection between the compartments so that reagent and sample may be interchanged. Other compartments such as waste compartment (36) may also be provided. Variants of the illustrated microfluidic circuit for joining the compartments and exchanging fluids between the compartments are readily within the scope of the invention. Sample processing steps could include extraction of the biological material and lysis of cells of interest, followed by filtration

and entry of the filtrate into a nucleic acid capture and elution module. Steps of capture, elution, amplification and detection are indicated without detail. Mesoscale devices for amplification and detection of a nucleic acid in a sample were first described in 1992 (U.S. Pat. No. 5,498,392 to Wilding, “Mesoscale Polynucleotide Amplification Device and Method”) and conventional mechanisms are known to those skilled in the art. These devices include various filters, pumps, vents, microfluidic channels, valves, and so forth. The device also optionally includes a display capability, although this function could be a simple visual indicator, or could be a complex interaction between the device and a docking site on an instrument that examines fluorescence of an array or a lateral flow strip, and so forth. Therefore, both stand-alone manual diagnostic applications and automated or semi-automated applications are envisaged. The inner workings of these devices are defined in various embodiments of the prior art. It should be noted that the claimed invention is not limited to a particular embodiment of the inner workings, and that applications for devices used in performing chemical or immunoassays are also anticipated. Devices may be built to assay for bioassay target molecules indicative of pathological conditions and biological threats of any kind

[0076] Sealing closure 34 comprises a gasket or gasket layer 35. In this embodiment, the guide track 8 serves also to force a tight seal between the gasket material and the swab receiving orifice 6, thus forming a fluid-tight seal over swab capture chamber 33. Following capture, the swab is treated by flowing extraction reagent or buffer in and out of the swab receiving chamber. The extraction buffer may include detergents, solvents such as water, and water in combination with DMSO, NMP, DMF, Formamide, THF, and detergents, co-detergents, cosolvents, proteolytics, sulphydryl-reducing agents such as n-acetyl-cysteine and dithiothreitol, selective nucleases, mucopolysaccharidases, cellulases, proteases, and the like. A discussion of mucolytics is provided in United States Patent Application 2004/0175695 to Debad. Mechanical agitation is important, and may be enhanced by sonication, such as with piezoelectric transducers. For reciprocal flow, air in the chamber can be vented through the waste sequestration chamber or at a secondary vent site. Optionally, the swab receiving chamber may contain active pump elements in tandem pairs, operating in alternation by positive and negative displacement, so that venting is not required. The structure of these paired pump elements consists of elastomeric or flexible diaphragms and the operation requires merely that as the diaphragm of one pump element is compressed, the other diaphragm is distended, so that the fluid is forced back and forth between the two pump elements. The diaphragms may be operated manually, hydraulically, electrostatically, magnetically, or pneumatically as is known in the art.

[0077] An important capacity of any such device is the sequestration of medical waste. The device will typically contain buffer and bioactive reagents for sample processing and analysis and all such material is best viewed as biohazardous. Ideally, all such waste is retained in the sealed body of the device and can be disposed of without hazard by autoclaving or incinerating the device itself. Shown here is a waste chamber (36) that would in operation be vented. Such vents as are permeable to air but not to liquid are well known. Added isolation is possible using a flexible diaphragm as described in co-assigned US Patent Document “Integrated Nucleic Acid Assays”, where fully operative details of assay systems of this